

occurring at a second frequency that is higher than said first frequency, disposed in the generally circumferential space between said first and second loop containing sections and alternately joined to said first and second loop containing sections, said first, second and third loop containing sections forming a plurality of cells and alternating sinusoidal patterns, and said first and second loop containing sections being joined together through said third loop containing section without connection directly between said first and second loop containing sections.

### **REMARKS**

Reconsideration of this application, as amended is respectfully requested. Claims 1, 6, 11, 16, 21, and 26 have been amended. New claims 45-49 have been added. Support for this amendment is found throughout the specification and drawings, for example, at page 8, lines 9-29; page 12, lines 13-27 and page 16, lines 29-30 and Figures 3 through 15. No new matter has been added.

1. The Examiner has objected to Figure 8 and the Brief Description of the Drawing section. The Examiner stated that the illustration which is old requires a designation such as "Prior Art". Applicants request withdrawal of the objections based on the enclosed proposed drawing correction in view of the following explanation.

As clearly shown in Figure 7, Figure 8 is an enlargement of a section of Figure 7. For the Examiner's convenience a marked-up enlargement of Figure 7 is attached to show the area illustrated in Figure 8. Pursuant to the attached Request, applicants respectfully request substitution of the originally filed Figure 8 with the corrected version of Figure 8, submitted herewith, and withdrawal of the objection is respectfully requested. No new matter has been

added. Support for this correction is found on page 6, line 25; page 14, lines 26-30; page 15-16; and Figure 7.

2. The Examiner objected to claim 1 for informalities concerning recitation of the third loop containing section. It is believed the amendments to claim 1 obviate these informalities, and applicants request withdrawal of the objection.

3. The Examiner also rejected claim 1 under 35 U.S.C. §112, second paragraph, as being indefinite for lacking proper antecedent basis. It is similarly believed that the amendments to claim 1 obviate this rejection and withdrawal of the rejection is respectfully requested.

4. Claims 1, 2, 4, 6, 7, 9, 11-12, 14, 16-17, 19, 21-22, 24, 26-27, 29, and 42-44 have been rejected under 35 U.S.C. §102(e) as being anticipated by Berry (US 6,231,598). As explained hereafter, applicants respectfully submit that the pending claims as presently amended are not anticipated by Berry.

The Berry reference describes a stent having a series of zig-zag elements, some of which are connected by longitudinal struts. These straight longitudinal struts connect adjacent circumferential elements forming rigid sections along the stent. The longitudinal struts provide rigidity rather than flexibility to a stent, since the longitudinal struts in Berry are meant to maintain longitudinal orientation during and after expansion of the stent. Stents having this structure are commonly referred to as "articulated" stents. When these prior art articulated stents are routed through curvatures in the patient's arterial pathway, the stiff sections remain rigid and do not bend, only the flexible connectors bend. Thus, the rigid sections of the Berry stent create a variable level of flexibility along the length of the stent. The instant invention, in contrast, is a uniformly flexible stent having a uniform level of flexibility along the length of the stent.

*Assuming arguendo*, the Berry reference is viewed in accordance with the Examiner's position (see page 3 of the Official Action dated Sept. 24, 2002), the Berry reference still does not teach or suggest a first loop containing section formed of a single continuous generally sinusoidal element, nor is it comprised of a uniformly distributed structure which results in a stent having uniform flexibility. Rather, the Berry stent contains a rigid section having two zig-zag elements directly connected by a rigid longitudinal strut. Further, the Berry reference does not teach or suggest a stent formed of a uniform mesh of triangular cells.

It is well settled that for prior art to anticipate under 35 U.S.C. §102, every element of the claimed invention must be identically disclosed, either expressly or under principles of inherency, in a single reference. *Corning Glass Works v. Sumitomo Elec.U.S.A., Inc.*, 9 U.S.P.Q.2d 1962, 1965 (Fed. Cir. 1989). Because Berry does not disclose the same structure as the instant claims, withdrawal of the rejection is respectfully requested.

As to claims 1 and 6, the Examiner has taken the position that Berry can be construed to anticipate these claims. Applicants respectfully disagree with this rejection. Berry does not teach or suggest a first and/or second loop containing section which is a single, continuous, generally sinusoidal pattern, as recited in claim 1. Similarly, Berry does not teach or suggest a plurality of first circumferential bands each of which is a single continuous, generally sinusoidal element, as recited in claim 6. Furthermore, Berry does not teach or suggest a stent wherein the first and second loop containing sections/ first circumferential bands are connected via the third loop containing section / second circumferential bands. Berry also does not teach or suggest the use of high and low frequency loop containing sections to provide rigidity and/or flexibility; the

Berry description is silent as to this feature. It should also be noted that because the illustrations in Berry are not to scale, they cannot be viewed as a teaching.

For all the foregoing reasons, Berry does not teach or suggest a stent as recited in independent claims 1 or 6, and therefore does not anticipate these claims. Moreover, when a reference does not anticipate an independent claim, it cannot anticipate the claim from which it depends. Therefore, Berry also does not anticipate dependent claims 2-5, 7-10 and 42-44 and applicants respectfully request reconsideration and withdrawal of this §102 rejection.

As to claims 11-12 and 14, the Examiner proposed a characterization of Berry's Figure 5 said to define a first loop section (colored in brown), a second loop section (colored in green) and a third loop section (colored in yellow). *See* page 4 of the Official Action dated Sept. 24, 2002. Applicants respectfully disagree with the rejection of the instant invention in light of this characterization.

Claims 11, 12 and 14 are directed to a stent which consists essentially of triangular cells. However, the Berry structure as proposed by the Examiner ignores additional elements found in the Berry reference. For example, Berry includes additional zig-zag elements and longitudinal struts, which do not form triangular cells and therefore do not fall within the scope of the instant claims. Also, the claims require the loop containing sections to form single sinusoidal elements which alternate circumferentially along the longitudinal axis of the stent. Again, the Berry reference describes additional elements which interfere with the alternating pattern and therefore do not teach or suggest a circumferentially alternating pattern of single sinusoidal elements. Therefore, the Berry reference does not teach or suggest the invention as claimed. For these reasons, applicants respectfully request reconsideration and withdrawal of this §102 rejection.

As to claims 16-17, 19, 21-22, and 24, the Examiner has an alternate proposed characterization (Fig. 1 and 5) of Berry, highlighted in red and green to denote first and second meander patterns, respectively. *See* page 3 of the Official Action dated Sept. 24, 2002.

Applicants respectfully disagree with the Examiner's rejection of the instant invention in light of this characterization.

Figure 5 of the Berry reference does not describe a stent as recited in claims 16, 17 or 19. These claims set forth a stent having first and second meander patterns which intertwine to form triangular cells so that the stent consists essentially of triangular cells. Berry does not teach or suggest a stent consisting of triangular cells. Rather, Berry discloses patterns (14) connected together through longitudinal struts (32). These sections containing the longitudinal struts do not form triangular cells and therefore do not fall within the scope of the claimed invention. Similarly, these longitudinal struts form rigid sections along the length of the stent, resulting in a stent that is not uniformly flexible. Applicants respectfully request reconsideration and withdrawal of this §102 rejection, in view of these distinguishing features.

Further, the Berry reference does not describe a stent as recited in claims 21, 22 and 24. The Examiner, in his highlighted version of Figure 5, indicates that a section containing two zig-zag elements connected by longitudinal struts is considered a "odd vertical meander pattern". Applicants respectfully disagree with this application of Berry. The claims specifically recite that the odd and even vertical meander patterns each consist of a single continuous generally sinusoidal element. Berry does not teach or suggest a stent having odd and even vertical meander patterns, each consisting of a single continuous generally sinusoidal elements.

Therefore, the Berry reference does not anticipate claims 21, 22 and 24. Reconsideration and withdrawal of this §102 rejection is respectfully requested.

As to claims 26-27, and 29, the Examiner has provided a drawing (Fig. 1 and 5 Berry) which illustrates another interpretation of the Berry reference. *See* page 5 of the Official Action dated Sept. 24, 2002. Applicants respectfully disagree with this interpretation. Claims 26, 27 and 29 require the members to form a uniform mesh of flexible cells. The enclosed spaces identified by the Examiner are interrupted by non-flexible cell sections, which prevent the formation of a uniform mesh of flexible cells. Therefore, Berry does not teach or suggest a stent having members which form a uniform mesh of flexible cells. Thus, Berry does not anticipate claims 26, 27 and 29. Applicants respectfully request reconsideration and withdrawal of this §102 rejection.

5. Claims 3, 5, 8, 10, 13, 15, 18, 20, 23, 25, 28, and 30 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Berry in view of Yang (U.S. 6, 120, 847). The Examiner stated that Berry does not disclose a stent coated with medicine for treatment purpose. The Examiner further stated that it would have been obvious to provide a medicine coating to Berry that is disclosed in Yang to achieve the characteristics as recited in the Applicants' claims.

Applicants respectfully traverse this rejection and submit that a *prima facie* case of obviousness has not been made and that the claims would not have been obvious over the references cited above.

As discussed in detail above, Berry does not teach or suggest the invention as claimed. For example, Berry does not teach or suggest a stent having a uniform mesh of flexible cells. Berry does not teach or suggest a stent having alternating single continuous, generally sinusoidal

elements. Berry does not teach or suggest first circumferential bands which are single sinusoidal elements, that are joined together through second circumferential bands without direct connection between each other. Finally, Berry is silent as to having higher frequency elements and the figures cannot constitute an affirmative teaching because they are not drawn to scale.

The Berry reference in combination with Yang does not render obvious the stent of the present invention having a coating as recited in claims 3, 5, 8, 10, 13, 15, 18, 20, 23, 25, 28, and 30. One skilled in the art reading these references would not be led to the instant invention, because neither Berry or Yang teach or suggest the basic stent of the invention. For these reasons, applicants respectfully request reconsideration and withdrawal of this §103 rejection.

**CONCLUSION**

It is respectfully submitted that the pending claims are patentable and in condition for allowance. Early and favorable reconsideration is earnestly solicited.

If any issues remain, or if the Examiner has any suggestions for expediting allowance of this application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

**AUTHORIZATION**

The Assistant Commissioner is hereby authorized to charge any additional fees that may be required for this response to Deposit Account 13-4500, Order No. 4303-4003US3, and is hereby petitioned for any extension of time that may be required to make this response timely. **A DUPLICATE OF THIS SHEET IS ATTACHED.**

Respectfully submitted,

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Date: February 25, 2003

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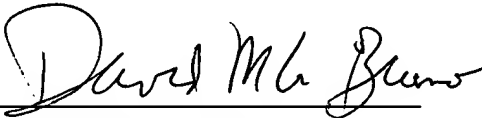
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**APPENDIX**

Please **amend** claims 1, 6, 11, 16, 21 and 26 as follows:

1.(Twice Amended) A uniformly flexible stent for holding open a blood vessel comprising:

a. a first loop containing section, [the] said first loop containing section arranged generally in [the] a circumferential direction, the loops in said first loop containing section occurring at a first frequency;

b. a second loop containing section, [the] said second loop containing section arranged generally in the circumferential direction, the loops in said second loop containing section also occurring at said first frequency;

c. at least one of said first and second loop containing sections formed of a single, continuous, generally sinusoidal pattern; and

[c.] d. a third loop containing section, [the] said third loop containing section arranged generally in the circumferential direction, the loops in said third loop containing section occurring at a second frequency that is higher than said first frequency, disposed in the generally circumferential space between said first and second loop containing sections and alternately joined to said first and second loop containing sections, said first, second and third loop containing sections forming a plurality of cells and alternating sinusoidal patterns, and said first and second loop containing sections being joined together through said third loop containing section without connection directly between said first and second loop containing sections;

[d.] e. [wherein] the loops in said first, second and third loop containing sections

[are] being disposed and adapted to cooperate so that, components of said third loop containing section contribute to the cell's elongating or shortening when the stent is flexed in a vessel.

6. (Twice Amended) A uniformly flexible stent for widening a vessel in the human body comprising:

- a. a plurality of first circumferential bands, each containing a single, continuous, generally sinusoidal pattern of loops at a first frequency;
- b. a plurality of second circumferential bands, each containing a pattern of loops at a second frequency higher than said first frequency, alternating with said first circumferential bands and periodically coupled [thereto] to said first bands to form cells, said first circumferential bands being joined together through said second circumferential bands without direct connection of any first circumferential bands to another first circumferential band;
- c. [wherein] patterns of loops in said bands [are] being disposed and adapted to cooperate so that[,] the higher frequency band components contribute [most] more than lower frequency bands to [of the] deformation during flexing of the stent.

11. (Amended) A stent for holding open a blood vessel [formed of] consisting essentially of a plurality of triangular cells, each triangular cell comprising:

- a. a first loop containing section, the first loop containing section arranged generally in the circumferential direction;

b. a second loop containing section joined to the first loop containing section at a first junction point; and

c. a third loop containing section joined to the first loop containing section at a second junction point and joined to the second loop containing section at a third junction point, the first and second loop containing sections forming a first single sinusoidal pattern and the third loop containing section forming a second single sinusoidal pattern, said first and second sinusoidal patterns alternating circumferentially along the longitudinal axis of the stent;

d. wherein loops in said cells are disposed and adapted to cooperate so that, when the expanded stent is in a curved vessel, cells on the outside of the curve open in length, but narrow circumferentially whereas cells on the inside of the curve shorten in length but widen circumferentially.

16. (Amended) A stent for widening a vessel in the human body comprising:

a. a plurality of first meander patterns, said first meanders comprising alternating odd and even first meander patterns, said odd and even first meander patterns being out of phase;

b. a plurality of second meander patterns intertwined with the first meander patterns to form triangular cells, said triangular cells forming a uniform mesh consisting essentially of said cells along the stent, said first meander patterns and said second meander patterns disposed and adapted to cooperate so that after expansion of said stent, when said stent is disposed in a curved vessel, cells on the outside of the curve open in length, but narrow

circumferentially whereas cells on the inside of the curve shorten in length but widen circumferentially.

21.(Amended) A multicellular stent for holding open a lumen, comprising:

- a. a plurality of even and odd vertical meander patterns, the odd vertical meander patterns being located between every two even vertical meander patterns and being out of phase with the even vertical meander patterns, said even and odd vertical meander patterns each consisting of a single continuous, generally sinusoidal element;
- b. a plurality of even and odd horizontal meander patterns, the odd horizontal meander patterns being located between every two even horizontal meander patterns,
- c. [wherein] the vertical meander patterns [are] being intertwined with the horizontal meander patterns to form a plurality of triangular cells;
- d. [wherein] said horizontal meander patterns and said vertical meander patterns [are] being disposed and adapted to cooperate so that after expansion of said stent[, when said stent is disposed in] within a curved lumen, cells on the outside of the curve open in length, but narrow circumferentially whereas cells on the inside of the curve shorten in length but widen circumferentially.

26.(Amended) An expandable stent comprising a plurality of enclosed flexible spaces, each of the plurality of enclosed flexible spaces including:

- a) a first member having a first end and a second end;
- b) a second member having a first end and a second end;

- c) a third member having a first end and a second end;
- d) a fourth member having a first end and a second end; the first end of the first member communicating with the first end of the second member, the second end of the second member communicating with the second end of the third member, and the first end of the third member communicating with the first end of the fourth member;
- e) the first member and the second member with the curved portion at their ends forming a first loop;
- f) the third member and the fourth member with the curved portion at their ends forming a second loop;
- g) a fifth member having a first end and a second end;
- h) a sixth member having a first end and a second end;
- i) a seventh member having a first end and a second end;
- j) an eighth member having a first end and a second end;
- k) a ninth member having a first end and a second end; and
- l) a tenth member having a first end and a second end, the first end of the fifth member communicating with the second end of the first member, the second end of the fifth member communicating with the second end of the sixth member, the first end of the sixth member communicating with the first end of the seventh member, the second end of the seventh member communicating with the second end of the eighth member, the first end of the eighth member communicating with the first end of the ninth member, the second end of the ninth member communicating with the second end of the tenth member, and the first end of the tenth member communicating with the second end of the fourth member;

- m) the fifth member and the sixth member with the curved portion at their ends forming a third loop;
- n) the seventh member and the eighth member with the curved portion at their ends forming a fourth loop; and
- o) the ninth member and the tenth member with the curved portion at their ends forming a fifth loop, wherein the first, second, third, fourth, fifth, sixth, seventh, eighth, ninth, and tenth members form a uniform mesh of flexible cells; and  
[wherein,] when the expanded stent is in a curved lumen, cells on the outside of the curve at communication points of the first and fifth and fourth and tenth members[, the cell opens up increasing the] increase in length [of the cell] and at each of the first through fifth loops, the adjoining members come closer to each other, to cause the cell to [become narrower] narrow circumferentially [and compensating] to compensate for the increase in length, whereas cells on the outside of the curve at communication points of the first and fifth and fourth and tenth members[, the cell closes down decreasing the] decrease in length [of the cell] and at each of the first through fifth loops, the adjoining members move apart, to cause the cell to become wider circumferentially and compensate for the decrease in length.